MAR 17 2014

510(k) Summary

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Cortex SATURN Dental Implant System

1. GENERAL INFORMATION

Date Prepared:	March 17th , 2014
Sponsor:	Cortex Dental Implants Industries Ltd. P.O. Box 125, Industrial Zone Shlomi, 22832 Israel
Contact:	Mrs. Simha Sibony, **Qualitech** P.O.Box 12082 Nahariya 2201202 ISRAEL Cell: +972-52-654-6625 Fax: +972-4-9000389 Simha.QualiTech@gmail.com
Trade Name:	SATURN Dental Implant System
Common Name:	Endosseous Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Class:	II
Product Code:	DZE/NHA
CFR section:	21 CFR section 872.3640/872.3630
Device Panel:	Dental
Legally marketed predicate devices:	Nobel Active – K071370 Straumann Bone Level Implant – K121131
Intended Use:	The SATURN Dental Implant System is intended for surgical placement in the maxillary or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous or partially edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth restoration for immediate loading after extraction when good primary stability is achieved and with appropriate occlusal loading. The procedure can be accomplished in a one-stage or two-stage surgical operation.

2. DEVICE DESCRIPTION

The SATURN Dental Implant employs a new strategy that of extended sub-crestal threads, expanded out in a wing-like effect to engage socket walls mid-crestally. The implants material composition is: TI 6AL 4V – ELI

The system consists of a variety of bone screw implants in three diameters ø 3.8, 4.2, 5.0 mm diameter. Each respective diameter is available in various lengths from 8 mm to 16mm. The bone screw (implant) is connected to the abutment via an internal connecting screw while the alignment of the abutment is determined.

SATURN Dental Implants are tapered internal hex implants, designed to enable easy insertion, while supporting initial stability. The variable thread (coil) design enables self-tapping, thus providing solution for a variety of bone conditions.The internal hexagon helps to minimize rotation. SATURN Dental Implant System offers a solution for immediate placement and immediate loading.

The SATURN Dental Implant System is cleared for marketing in Europe. The device was implanted in thousands of patients in Israel and Europe.

Materials:
The components are manufactured from titanium alloy (Ti 6Al 4V ELI) per ASTM F136.

Function:
The SATURN Dental Implant System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous or partially edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.
The System is intended to be used in either single tooth or multiple teeth restoration for immediate loading after extraction when good primary stability is achieved and with appropriate occlusal loading.
The procedure can be accomplished in a one-stage or two-stage surgical operation.

3. INTENDED USE

The SATURN Dental Implant System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous or partially edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

The System is intended to be used in either single tooth or multiple teeth restoration for immediate loading after extraction when good primary stability is achieved and with appropriate occlusal loading. The procedure can be accomplished in a one-stage or two-stage surgical operation.

4. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Saturn Dental Implant System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances. Specifically the intended us of all three systems is to restore chewing function by insertion of the implant into the maxilla or mandible to support single crowns or multi-unit restorations.

	Saturn	Nobel Active	Straumann
Material	Titanium	Titanium	Titanium alloy
Diameters	3.8-5.0mm	3.5-4.3 mm	4.1-4.8mm
Lengths	8-16 mm	10-15mm	8-14mm
Form	Root form	Root form	Root form
Insertion	Self Tapping	Self tapping	Self tapping

5. NON-CLINICAL TEST

Static and dynamic compression performance test was conducted per ISO 14801:2007- Dentistry-Implants- Dynamic fatigue test for Endosseous Dental implants.

The worst case scenario was chosen based on the FDA guideline "Class II Special Controls Guidance Document: Root- form for Endosseous dental implants and Endosseous dental Implant Abutments".

Fatigue test of the longest implant(16mm) in combination with the highest angled abutment(30°) was conducted.

The results of this testing indicate that the SATURN Dental Implant System is equivalent to the predicate devices cited in this submission.

6. CLINICAL TEST

Clinical Evaluation of SATURN Dental Implant System Case Reports:

Long-term results of several patients implanted with the SATURN Dental Implant System were presented and support the biomechanical theory concerning the loading on the implant. The implant wing reduces the pressure on the implant neck resulting in less absorption in the neck. The cases presented in this report show no bone loss in the neck of the implanted SATURN.

7. CONCLUSION

The results of the testing conducted on the Saturn Dental Implant System demonstrated that the system is substantially equivalent to the named predicated devices in terms of functional, mechanical properties, indications for use and material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 17, 2014

Cortex Dental Implants Industries Ltd.
C/O Mrs. Simha Sibony
Regulatory Affairs and QA Consultant
Qualitech
P.O.Box 12082
Nahariya 2201202 ISRAEL

Re: K131258
Trade/Device Name: SATURN Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 10, 2014
Received: February 14, 2014

Dear Mrs. Sibony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131258

Device Name: SATURN Dental Implant System

Indications for Use:

The SATURN Dental Implant System is intended for surgical placement in the maxillary and/or the mandibular arch, to support crowns, bridges, or over dentures, in edentulous or partially edentulous patients. It is intended to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

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The procedure can be accomplished in a one-stage or two-stage surgical operation.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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